

REMARKS/ARGUMENTS

Claims 19 through 31 are currently pending. Claims 1-18 have been cancelled. Claims 32-45 are new and are provided solely to more fully claim the invention. Claim 19 has been amended herein to correct antecedent basis for the term “mixture”. No new matter has been added by way of these amendments.

Rejection of Claims 19, 23 through 25 and 27 through 31 under 35 U.S.C. § 103(a)

Claims 19, 23 through 25 and 27 through 31 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,485,760, issued to Matsuyama (hereinafter “Matsuyama”) in view of U.S. Patent No. 5,431,916, issued to White (hereinafter “White”) and U.S. Patent No. 6,303,586, issued to McPeak (hereinafter “McPeak”).

Applicants respectfully traverse this rejection for at least the following reasons.

Matsuyama Does Not Disclose The Use Of Corosolic Acid In Combination With Rice Bran Oil And Contained Within A Soft Gel Capsule

Matsuyama discloses a method of inhibiting an increase in blood sugar level comprising an extract of *Lagerstroemia speciosa* leaves in an aqueous or aqueous ethanol solution. Matsuyama does not discuss making a formulation for a soft gel. Matsuyama does not describe using rice bran oil as a carrier. Matsuyama does not describe adding a filler to the rice bran oil carrier and Matsuyama does not describe encapsulating the mixture in a soft gel capsule.

White Teaches Against The Combination Made By The Office

White teaches against the use of acids in soft gels. Specifically, White discloses the use of tri-esters paired with polyvinylpyrrolidone to solubilize and suspend pharmaceutically active acids. Col. 1, lines 45-49. Further, White states, “strong acids . . . react with hydroxylated and poly-hydroxylated solvent and plasticizer species such as propylene glycol, polyethylene glycols and glycerin . . . these tri-ester polyvinylpyrrolidone systems allow for the facilitated selection of a plasticizer, by being nonsolvents for glycerin and possibly other plasticizer commonly used in soft gelatin capsule manufacturing” Col. 2, line 7-22. Thus, White specifically teaches that lacking a two-part solvent system comprising both tri-esters and polyvinylpyrrolidone acid

contents of soft gel capsules will both degrade the soft gel mantle as well as react with the capsule allowing “migration of the plasticizer from the soft gelatin shell into the pharmaceutically acceptable active/solvent fill.” Col. 2, lines 24-26.

Combining White With Matsuyama Does Not Yield The Present Invention

While White teaches against using Corosolic acid in soft gel capsules, were the disclosure of Matsuyama combined with White, the combination would yield Corosolic acid in combination with tri-esters *and* polyvinylpyrrolidone. Applicants point out that the instant invention does not rely on tri-esters or polyvinylpyrrolidone as solvents for the corosolic acid. Thus, for at least these reasons, one of skill in the art would not combine White with Matsuyama. If White is combined with Matsuyama, the product would not be the instant invention which lacks tri-esters or polyvinylpyrrolidone.

McPeak Does Not Rectify The Deficiencies Of Matsuyama And White

McPeak describes a method for controlling blood glucose levels in mammals comprising a stabilized rice bran derivative. McPeak does not discuss or even mention the use of rice bran oil. Independent Claim 19 requires rice bran oil that is heated to about 35° C in a container. In contrast, McPeak describes the rice bran component as “finely granulated, light tan in color.” Col. 5, lines 18-20. Further, McPeak describes an extraction technique, which yields an insoluble fraction that is dried and ground into a powder and a soluble fraction that is also dried. When used, the rice bran derivatives are administered by sprinkling on food, comprising an ingredient in a cereal, incorporation into a baked product, pasta, dessert snacks or high fiber food. Thus, McPeak not only does not describe an oil from rice bran. McPeak only describes a water soluble component or a water insoluble component both of which are dried to a powder and used as food additives. McPeak does not describe or discuss the use of an oil component as a carrier or an oil. Thus, McPeak does not teach the limitations missing from Matsuyama and White.

Therefore, for at least the reasons described above, because White teaches against the use of pharmaceutically active acids in soft gel capsules except when combined with tri-esters or polyvinylpyrrolidone and because the combination made by the Office would result in a soft gel capsule containing a dried rice bran powder mixed with tri-esters or polyvinylpyrrolidone and

corosolic acid and because independent claim 19 requires rice bran oil, a filler and corosolic acid contained in a soft gel capsule, the rejection of claims 19, 23-25 and 27-31 is overcome and should be withdrawn.

Rejection of Claims 20 through 22 under 35 U.S.C. § 103(a)

Claims 20 through 22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Matsuyama, in view of White and McPeak as applied to claims 19, 23 through 25 and 27 through 31 above and further in view of U.S. Patent No. 3,683,088, issued to Walter (hereinafter “Walter”), U.S. Patent No. 3,665,009, issued to Dickinson (hereinafter Dickinson), and U.S. Patent No. 6,407,068, issued to LaGrone (hereinafter “LaGrone”).

Applicants respectfully traverse this rejection for at least the following reasons.

As discussed above, neither Matsuyama, White, nor McPeak alone or in combination teach all the elements of independent Claim 19 from which claims 20-22 depend. Further, the addition of Walter, Dickinson, and LaGrone does not remedy the deficiencies of Matsuyama, White, nor McPeak as applied to independent Claim 19 or claims depending therefrom. Specifically, Walter describes the inclusion of beeswax in a soft gel capsule. Walter does not discuss the use of corosolic acid or rice bran oil. Dickinson, similarly, merely describes the inclusion of beeswax in a soft gel capsule. LaGrone merely provides a reference indicating that silica prevents diabetes in BB-rats. LaGrone provides no foundation for the use of silica in combination with corosolic acid, rice bran oil or beeswax encapsulated in a soft gel capsule. Neither Walter, Dickinson, nor LaGrone provide any teaching for the inclusion of beeswax or silica combined in a soft gel capsule with rice bran oil and corosolic acid. Therefore, lacking the elements of independent claim 19 and further lacking any motivation or teaching to use rice bran oil as a carrier for corosolic acid in a soft gel, which is absent from Matsuyama, White, and McPeak, the rejection of Claims 20-22 is overcome and should be withdrawn.

Rejection of Claim 26 under 35 U.S.C. § 103(a)

Claim 26 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Matsuyama, in view of White, McPeak, Walter, Dickinson, and LaGrone, as applied to claims 19

through 25 in further in view of U.S. Patent No. 5,980,902, issued to Shanmugasundaram (hereinafter “Shanmugasundaram”).

Shanmugasundaram does nothing to remedy the deficiencies of Matsuyama, White or McPeak with regard to the use of corosolic acid in combination with rice bran oil contained in a soft gel capsule as is required by independent claim 19. Thus, the inclusion of Shanmugasundaram does not render obvious the use of *Gymnema sylvestre* as required by dependent claim 26. Therefore, the rejection is overcome and should be withdrawn.

Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

This application now stands in allowable form and reconsideration and allowance is respectfully requested. If a telephonic consultation would help to expedite the processing of the application, the Examiner is urged to contact the attorney below at the Examiner's convenience.

This response is being submitted on or before October 30, 2007, with the required fee of \$525.00 for a three-month extension of time, making this a timely response. It is believed that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

Respectfully submitted,

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Date: October 12, 2007

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